

Attorney Docket No.: **KUZ-0024**
Inventors: **ITO et al.**
Serial No.: **10/531,433**
Filing Date: **April 15, 2005**
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REMARKS

Claims 2-3, 6-7, 13-14, 16-17 and 21-24 are pending in the instant application. Claims 2-3, 6-7, 13-14, 16, 17 and 21-24 have been rejected. Claims 21 and 22 have been amended. New claims 25-28 have been added. Support for these amendments is provided in teachings in the specification for example at page 10, lines 1-2 and canceled claims 4 and 20. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Rejection of Claims under 35 U.S.C. 103(a)

Claims 2-3, 6-7, 13-14, 16-17 and 21-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,814,032 issued to Hori et al. ("Hori").

Applicants respectfully traverse this rejection.

Claim 21 of the instant patent application has been amended to be drawn to a transdermal patch for external use having a backing layer and a pressure-sensitive adhesive layer formed on one surface of the backing layer, consisting essentially of polyisobutylene, a mineral oil and fentanyl as an active ingredient in the pressure-sensitive adhesive layer, contents of polyisobutylene and fentanyl in the pressure-sensitive adhesive layer respectively ranging from

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75.2 to 94.2% by mass and 1 to 6% by mass while the content of the mineral oil being from 0.25 to 0.05 parts by mass based on polyisobutylene, wherein the pressure-sensitive adhesive layer does not contain a hydrophilic polymer.

Claim 22 of the instant patent application has been amended to be drawn to a transdermal patch for external use having a backing layer and a pressure-sensitive adhesive layer formed on one surface of the backing layer, consisting essentially of polyisobutylene, a mineral oil, a percutaneous absorption enhancer and fentanyl as an active ingredient in the pressure-sensitive adhesive layer, contents of polyisobutylene and fentanyl in the pressure-sensitive adhesive layer respectively ranging from 75.2 to 94.2% by mass and 1 to 6% by mass while the content of the mineral oil being from 0.25 to 0.05 parts by mass based on polyisobutylene, wherein the pressure-sensitive adhesive layer does not contain a hydrophilic polymer.

Support for this amendment can be found in the specification at, for example, page 10, lines 1-2, wherein it is made clear that a hydrophilic polymer is not required as well as the Examples beginning at page 13 of the specification, none of which contained a hydrophilic polymer.

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In contrast, the Hori patent teaches as an essential element to the adhesive layer of their transdermal patch, 5 to 50% by weight of a hygroscopic material, also referred to as a water-absorbing polymer at col. 4, line 40 of the Hori patent.

Accordingly, the Hori Patent provides no reasonable expectation of success with respect to the instant claimed transdermal patch which does not contain as an element a hydrophilic (water-absorbing) polymer, but which still demonstrates excellent adhesive property, cohesive property, adhesion property and remaining of adhesive masse to the skin. See Table 1 and page 20 of the instant specification.

As acknowledged by the Examiner in the instant Office Action at page 4, the omission of an ingredient may be an indicia of unobviousness. Also see MPEP 2144.04 which states the omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Clearly, the claims as amended, which omit the inclusion of a hydrophilic polymer, are unobvious over the Hori Patent. As demonstrated by the Examples of the instant patent application, transdermal patches of the present invention without a hydrophilic polymer exhibit excellent adhesive property, cohesive property, adhesion property and remaining of adhesive mass

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to the skin. This is clearly unexpected over the Hori patent which teaches a water-absorbing polymer to be required for skin adhesive properties and low skin irritating properties.

Accordingly, the instant claimed invention is clearly unobvious over the Hori patent.

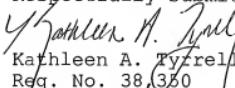
Withdrawal of this rejection under 35 U.S.C. 103(a) is respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Accordingly, favorable reconsideration and subsequent allowance of all pending claims is earnestly solicited.

Respectfully submitted,


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